



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0001]

Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery--Influences of Sex and Gender; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Office of Women's Health, Center for Drug Evaluation and Research, and Center for Tobacco Products are announcing the following conference entitled "Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery - Influences of Sex and Gender." The purpose of the conference is to discuss the biological (sex) and sociological (gender) influences on misuse, abuse, and cessation of opioids and tobacco. Researchers, educators, and clinicians may benefit from attending this multidisciplinary review and update on opioid and tobacco.

DATES: The two-day conference will be held on September 27, 2018 (8:30 a.m. - 4:00 p.m.) and September 28, 2018 (8:30 a.m.-4:00 p.m.). See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The conference will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503-A), Silver Spring, MD 20993. Entrance for the conference participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Gwendolyn Jones, Food and Drug Administration, Bldg. 32, Rm. 2333, 10903 New Hampshire Ave., Silver Spring, MD 20993, OWH_OandNConf@fda.hhs.gov, 301-796-9940.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is responsible for protecting the public health by assuring the safety and efficacy of FDA-regulated products. This conference will provide the Agency with further insight into the devastating public health crises caused by pervasive opioid and tobacco use. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. Many of the drug overdose deaths (more than 6 out of 10) involve an opioid. Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. Of the 63,632 drug overdose deaths in 2016, 66.4 percent (42,249) involved opioids, with increases across age groups, racial/ethnic groups, urbanization levels, and multiple states. Combustible cigarettes have been identified as the dominant cause of tobacco-related disease and are responsible for more than 20 million premature deaths since the first Surgeon General's report in 1964. Together, opioid and tobacco use are the leading causes of preventable disease and death in the United States, and women are increasingly affected. Sex and gender differences may influence susceptibility to substance abuse, which could have implications for optimal prevention and treatment. Gender influencers also impact public health from a familial and environmental

perspective. Researchers, educators, and clinicians must be able to recognize and consider both sex and gender differences to identify and treat women most at risk.

II. Topics for Discussion at the Conference

The conference will include presentations and panel discussions by experts in the field of opioid and tobacco research, professional education, and clinical care on the biological (sex) and sociological (gender) influences on misuse, abuse, and cessation of opioids and tobacco. Each panel discussion will have a Q&A session to respond to questions from in-person attendees.

III. Participating in the Conference

Registration: To register for the Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery - Influences of Sex and Gender, please visit the following website: <https://www.eventbrite.com/e/scientific-conference-opioid-and-nicotine-use-dependence-and-recovery-influences-of-sex-and-gender-tickets-47087275308>.

Registration is free and in-person seating is limited. The conference will also be available for viewing via webcast. Persons interested in attending or viewing this conference must register online by September 24, 2018, 5:00 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please email Gwendolyn Jones at OWH_OandNConf@fda.hhs.gov (See FOR FURTHER INFORMATION CONTACT) no later than September 24, 2018.

Streaming Webcast of the public meeting: This public meeting will also be webcast and can only be viewed if registered. To register, please go to <https://www.eventbrite.com/e/scientific-conference-opioid-and-nicotine-use-dependence-and-recovery-influences-of-sex-and-gender-tickets-47087275308>.

recovery-influences-of-sex-and-gender-tickets-47087275308. Registrants will receive confirmation and information about accessing the webcast when they have been accepted. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Dated: July 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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